KURARAY MEDICAL INC.
Dental Material Department
12-39, 1-Chome, Umeda, Kita-ku, Osaka 530-8611, JAPAN
Phone : +81-6-348-2603
Facsimile: +81-6-348-2552

K012442

SEP 1 0 2001

510(k) SUMMARY

1. Submitter

1) Name	KURARAY MEDICAL INC.
2) Address	1621 Sakazu, Kurashiki, Okayama 710-8622, Japan
3) Contact person	Koji Nishida DENTAL MATERIAL DEPARTMENT
4) Date	July 23, 2001
5) Contact person in U.S.A.	Masaya Sasaki 30th Fl. Metlife Building, 200 Park Avenue, New York, NY 10166 Telephone : (212)-986-2230 1(800)-879-1676 Facsimile : (212)-867-3543

2. Name of Device

1) Proprietary Name	CLEARFIL SE BOND
2) Classification Name	Resin tooth bonding agent (21CFR 872.3200)
3) Common/Usual Name	Resin-based dental adhesive system

3. Predicate device:

Kuraray Co., Ltd. will transfer the medical device business and the relevant functions including manufacturing facilities to its subsidiary company named Kuraray Medical Inc. on October 1st 2001. The aim of 510(k) submission is to alter the name and address of manufacturer, and not to intend other changes.

The predicate device is as follow.

1. CLEARFIL SE BOND by Kuraray Co., Ltd. (K990040)

4. Description for the premarket notification

CLEARFIL SE BOND is classified into the resin tooth bonding agent, CFR 21 Section 872.3200, because it is a device composed of materials such as dimethacrylate monomers intended to painted on the interior of a prepared cavity of a tooth to improve retention of restorative materials.

5. Statement of the intended use

The intended uses of this device are as follows. They are completely the same as CLEARFIL SE BOND manufactured by Kuraray Co., Ltd. (K990040).

1) Direct filling restorations using light-curing composite or compomer
2) Cavity sealing as a pretreatment for indirect restorations
3) Treatment of hypersensitive and/or exposed root surfaces
4) Intraoral repairs of fractured facing crowns made of porcelain, hybrid ceramics or comosite resin using light-curing composite
5) Surface treatment of prosthetic appliances made of porcelain, hybrid ceramics and cured composite resin

6. Statement of the technological characteristics and safety

This device is essentially the same as CLEARFIL SE BOND manufactured by Kuraray Co., td. (K990040). Therefore the technological characteristics, chemical ingredients and safety of this device are completely the same as CLEARFIL SE BOND.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 0 2001

Kuraray Medical Incorporated
C/O Ms. Masaya Sasaki
Kuraray America, Incorporated
30th Floor Metlife Building
200 Park Avenue
New York, New York 10166

Re: K012442
Trade/Device Name: Modification To Clearfil SE Bond
Regulation Number: 872.3200
Regulation Name: Resin-Based Dental Adhesive System
Regulatory Class: II
Product Code: KLE
Dated: July 23, 2001
Received: July 31, 2001

Dear Ms. Sasaki:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (section 531-542 of the Act; 21); CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K012442

510(k) Number (if known): K012442

Device Name: CLEARFIL SE BOND

Indications for Use

CLEAFIL SE BOND is indicated for the following applications:

1) Direct filling restorations using light-curing composite or compomer
2) Cavity sealing as a pretreatment for indirect restorations
3) Treatment of hypersensitive and/or exposed root surfaces
4) Intraoral repairs of fractured facing crowns made of porcelain, hybrid ceramics or composite resin using light-curing composite
5) Surface treatment of prosthetic appliances made of porcelain, hybrid ceramics and cured composite resin

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Part 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012442